

On March 30, 1943, no appearance, responsive affidavit, or pleading having been filed, the court ordered that the defendant, his agents, servants, and employees, and all other persons in active concert or participation with him, be permanently enjoined and restrained from directly or indirectly introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce the article sold under the name Korjena, as then labeled, in violation of the Federal Food, Drug, and Cosmetic Act.

907. Misbranding of Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.).
Plea of guilty. Fine, \$200. (F. D. C. No. 5517. Sample Nos. 19250-E, 19370-E.)

On December 16, 1941, the United States attorney for the Western District of New York filed an information against Jerome V. Gladke, trading as the Korjena Medicine Co., Elmira, N. Y., alleging shipment on or about September 18, 1940, and January 10, 1941, from the State of New York into the State of Pennsylvania of a quantity of Korjena which was misbranded.

Analysis of a sample of the article showed that it contained phenolphthalein, compounds of calcium and magnesium, iodides, bile salts, and extracts of plant drugs including a strychnine-bearing drug.

The article was alleged to be misbranded in that the statements, "A Dependable Treatment for the Reduction of Excessive Fat * * * This Treatment is Guaranteed Dependable and may be taken with Complete Confidence * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results * * * This Treatment is dependable in normal conditions * * * All normal cases of excessive weight may confidently follow above directions," borne on the boxes containing the article, were false and misleading since they represented and suggested that the article was a dependable, safe, and adequate treatment for the reduction of excessive fat, whereas it was not a safe, dependable or adequate treatment for such purpose but might produce harmful results. The article was alleged to be misbranded further in that the statement, "Active Ingredients: Phenolphthalein, Calcium Iodide, Sodium Choleinate," borne on the boxes, was false and misleading since the said statement represented and suggested that phenolphthalein, calcium iodide, and sodium choleinate were the only active ingredients, whereas the article contained the active ingredient strychnine in addition to those named; in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of strychnine contained in it; in that its label failed to bear adequate directions for use since the directions, "Take 1 tablet after each meal * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results," were not suitable and appropriate directions for the drug, which was essentially a laxative; in that its labeling did not bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative and contained phenolphthalein and should not be used when abdominal pain, nausea, vomiting or other symptoms of appendicitis are present, and frequent or continued use might result in dependence on laxatives, and that it should be discontinued if a skin rash should appear.

On December 28, 1942, the defendant having entered a plea of guilty, the court imposed a fine of \$200.

908. Adulteration and misbranding of Bullock's System Self Treatment for Sinus and Catarrhal Infection. U. S. v. Henry Spangler (National Laboratories, Inc.). **Plea of nolo contendere. Sentence of 180 days in jail conditionally suspended.** (F. D. C. No. 7209. Sample No. 50930-E.)

This product, which was packed in a cardboard container, consisted of one can of Bullock's Antiseptic Healing and Cleansing Tonic, one jar of Bullock's Nasal Salve, one box of Bullock's Clear Head Tablets, one vial of Sneeze-It, and one bottle each of King Cold Knockout, Ear Oil, Special Sea Salt, and Bullock's Antiseptic Emollient, and a device which included a nasal atomizer of the common variety, an aluminum can with hose connection for irrigating the sinus, a measuring cup, and a thermometer.